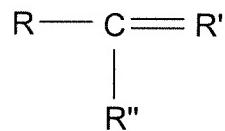


## REMARKS

Currently, claims 16, 18-21, and 39-48, including independent claim 16, are pending in the present application. Independent claim 16, for instance, is directed to an assay device for detecting the presence or absence of amines within a test sample. The assay device comprises a porous membrane that is in fluid communication with detection probes conjugated with an immunoreactive specific binding member for the analyte. The porous membrane defines a first detection zone within which a triarylmethane dye is immobilized and a second detection zone within which a capture reagent is immobilized. The triarylmethane dye is capable of undergoing a detectable color change upon reaction with one or more amines and has the following general structure:



wherein R, R', and R" are independently selected from substituted and unsubstituted aryl groups. The capture reagent is configured to bind to the analyte or specific binding member to generate a detection signal.

In the Office Action, independent claim 16 was rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent Application Publication No. 2006/0008921 to Daniels, et al. in view of U.S. Patent No. 7,014,816 to Miller, et al. and U.S. Patent No. 5,998,161 to Caillouette, et al. Daniels, et al. relates to immunochromatographic test strips in which multiple analytes can be detected simultaneously by using more than one semiconductor nanocrystal as a detectable label, each of which emits at a distinct wavelength (p. 1, ¶ [0002]). Specifically, the assays of Daniels, et al. include

semiconductor nanocrystals that have characteristic spectral emissions that can be tuned to a desired energy by varying particle size, size distribution, and/or compositions (p. 2, ¶ [0016]). The semiconductor nanocrystals of Daniels, et al. are used as detectable labels in flow-type assay devices that utilize a suitable absorbent, porous or capillary possessing material suitable thereto (p. 8, ¶ [0124]). Specifically, the assay of Daniels, et al. includes a capture reagent immobilized within a distinct capture region of a chromatographic medium. The capture reagent comprises a capture ligand capable of selectively binding a detection complex. This detection complex includes a detection ligand bound to a target moiety. Thus, upon binding of the detection complex to the capture ligand in the capture region, an immobilized capture complex is formed. (P. 2, ¶ [0021]-[0026]).

As correctly noted in the Office Action, Daniels, et al. completely fail to disclose certain limitations of the present claims, such as the use of a triarylmethane capable of undergoing a detectable color change upon reaction with one or more amines. Nevertheless, the Office Action cited Miller, et al. as teaching the detection of amines in a test sample.

Miller, et al., however, is directed to a device for detecting *food spoilage*, such as in red meat, pork, poultry, processed meat, and seafood products. (Col. 3). In stark contrast, Daniels, et al. is directed to an immunochromatographic test strip assay that is primarily useful for diagnosing a variety of human conditions and diseases, such as pregnancy (hCG present in urine); Down's syndrome (alpha-fetoprotein and acetylcholinesterase in amniotic fluid); myocardial infarction (cardiac markers such as troponin-T and myoglobin); sexually transmitted diseases including gonorrhea,

chlamydia, and syphilis (antigens associated with each organism present in blood and/or semen or vaginal secretions); hepatitis, including HAV, HBV and HCV (viral antigens characteristic of each type of virus present in blood, urine, and other bodily fluids); and HIV (viral antigens present in blood, urine and other bodily fluids). The mere fact that Miller, et al. describes a technique for detecting *food spoilage* would in no way whatsoever lead one of ordinary skill in the art to choose the colorimetric agent for use in the immunochromatographic test strip.

Notwithstanding the above, the Office Action asserts that it would have been obvious to include a detection zone that contains a colorimetric agent that undergoes a color change in the presence of amines as taught by Miller, et al. because it would provide “an effective means to indicate the presence of an unwanted biological agent . . . in a sample, particularly a food sample.” There is, however, no support for this conclusion. In fact, the position taken in the Office Action is tantamount to a finding that any possible detection agent for any conceivable purpose is “obvious” for use in a detection zone in the test strip of Daniels, et al. A proper analysis under 35 U.S.C. § 103 certainly does not permit such a position.

Furthermore, the fundamental principle of the assay of Daniels, et al. is that the analyte is heterogeneously separated from the test sample as it flows laterally through the test strip. In Miller, et al., however, detection is accomplished by simply contacting a sample with a polymer matrix saturated with the indicator compound. These detection systems are so vastly different that one of ordinary skill in the art would not have found it obvious to selectively pick-and-choose aspects from each reference in an attempt to achieve the limitations of the present claims.

Applicants also note that an analysis under 35 U.S.C. § 103 must include a consideration of the claimed invention as a *whole*. In this particular case, the present inventors have discovered that the integration of amine and analyte detection zones with a single assay device can allow for the simultaneous detection of multiple infection indicators, such as amines and analytes (e.g., C-reactive protein). The claim invention thus provides a relatively simple, compact and cost-efficient device for accurately detecting amines and other analytes within a test sample (e.g., vaginal fluid). Nothing in any of the references cited in the Office Action would lead one of ordinary skill in the art to make some sort of combination to achieve the claimed invention. Instead, it appears that the only reason for combining the references in the manner suggested in the Office Action is based on a hindsight analysis of the present application, which is not proper under § 103(a).

Thus, for at least the reasons set forth above, it is believed that the present application is in complete condition for allowance and favorable action, therefore, is respectfully requested. Examiner DiRamio is invited and encouraged to telephone the undersigned, however, should any issues remain after consideration of this Amendment.

Please charge any additional fees required by this Amendment to Deposit Account No. 04-1403.

Appl. No. 10/790,617  
Amdt. dated Feb. 9, 2009  
Reply to Office Action of Nov. 13, 2008

Respectfully requested,  
DORITY & MANNING, P.A.

  
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